SULZER*MEDICA*

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August 31, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair [Docket Number: 00N-1380]

Dir Sir or Madam:

Sulzer Spine-Tech, a manufacturer of medical devices for use in spinal fusion surgery, submits the following written comments regarding the regulation of human bone allografts. These comments were articulated at the public meeting on August 2, 2000.

Historically, Spine-Tech has been perceived as an advocate for increased regulation of allograft bone. However, it is the position of our company that regulation of human allograft as a medical device is not in the best interest of public health. We contend that existing regulations governing the use of human tissues intended for transplantation (21 CFR Part 1270) are adequate to address the public health risks associated with disease transmission and we urge the Agency to move swiftly to implement the forthcoming Good Tissue Practice (GTP) regulations. We do not believe there is a public health risk that can be addressed by treating human allograft bone as a medical device.

We do feel it is important to draw a distinction between allograft bone and those products created from elements of allograft bone that also consist of materials such as metal, synthetics or animal tissues. The FDA's treatment of these products as medical devices or biologics is appropriate from our perspective.

As for minimal manipulation and homologous use, Spine-Tech applauds the FDA's efforts to develop a mechanism by which tissue products can be distinguished from devices, but we are concerned that the definitions fail to provide clear distinction. Ultimately, we find the statements

expressed by AdvoMed at the Aug 2, 2000 Human Bone Allograft meeting persuasive and so agree with its position that the definitions should be eliminated.

However, recognizing the specific request made by the Agency in preparation for this meeting, we provide the following interpretation of 'minimal manipulation' as it relates to human allograft bone used as structural graft for spinal reconstruction and repair. We suggest that any processes that do not alter the essential micro-structural elements of allograft bone (i.e. the collagenous and mineral components) are processes of minimal manipulation. When these elements remain, we contend that bone should be regulated as a tissue.

Thank you for your consideration of these comments.

Sincerely,

Daniel R. Mans
VP of Clinical and Regulatory Affairs
Sulzer Spine-Tech

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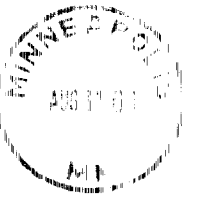

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